

### **REMARKS**

This Amendment responds to the Office Action dated June 17, 2004, in which the Examiner rejected claims 17 and 18. Reconsideration and reexamination are respectfully requested in light of the foregoing amendments and the following remarks.

In response to the objection posed by the Examiner, applicants have amended the specification to recite the priority application claimed herein. Applicants submit that the objection may be withdrawn.

Applicants note that the Examiner has noted an informality on page 19, lines 25-26 relating to fractions identified in the specification. Applicants respectfully traverse the objection.  $R_t 8_1$ ,  $R_t 10_1$ ,  $R_t 14$  and  $R_t 17$  on page 19, lines 25-2 refer to retention times. The fractions are collected at the respective retention time. With the retention times, one can see from Figure 4 which peaks are collected. The text on page 19, line 32, page 20, line 5 and page 20, line 15 provide the content of the respective fractions. Figure 4 mentions with which peaks these compounds correlate. It is respectfully submitted that there is sufficient antecedent basis for the use of  $R_t 8_1$ ,  $R_t 10_1$ ,  $R_t 14$ , and  $R_t 17$ . Applicants therefore request reconsideration and withdrawal of this objection to the specification.

Concerning the objection concerning the alleged omission of Table 4, applicants are reviewing the issue, and respectfully request that any amendment to the specification be deferred temporarily. Applicants will either amend the specification to remove references to Table 4 or will forward the information for inclusion in the specification, without adding new matter. Applicants appreciate the Examiner's

indulgence in allowing applicants the opportunity to carefully review this issue and respond as necessary at a later date.

Regarding the rejection under 35 U.S.C. §112, second paragraph, based upon use of "such as" in claim 17, applicants have deleted this phrase. The rejection can therefore be withdrawn.

Turning to the rejections under 35 U.S.C. §112, first paragraph, the Examiner asserts that the disclosure in the specification does not enable a person of ordinary skill to practice the invention commensurate in scope with the claim. The Examiner asserts that the pharmaceutical art is highly unpredictable, and that the specification fails to show that all of the claimed oxidation products of urocanic acid would be effective pharmaceutical agents to modulate immune responses.

In response, applicants maintain that the amended claims are not directed towards achieving a therapeutic effect. It is submitted that the applicants are entitled to a claim directed to a method using "a product of oxidation of urocanic acid with a reactive oxygen species." Applicants separated the products of such a reaction and identified no less than three different compounds that have the specified activity (i.e. imidazole-4-carboxyaldehyde, imidazole-4-acetic acid, or imidazole-4-carboxylic acid). Results with these compounds are depicted in Figure 5.

Further, applicants demonstrated that the three compounds are not the only compounds with the specified activity. The same Figure 5 shows that a mixture of the three compounds (Im-mix) was not as effective as POMixIII which is a similar mixture but now also includes other unidentified oxidation products of UCA (see legend to

Figure 5 on page 24).

The specification provides ample teaching for the person skilled in the art to identify further oxidation products. It is therefore submitted that the applicant is entitled to a claim directed to a method involving product of oxidation of urocanic acid with a reactive oxygen species. The specification describes that also the salts of the imidazole compounds of claim 18 can be used to achieve the desired effect. Thus teaching of the invention is not limited to the compounds of claim 18. It is therefore submitted that the specification is enabling for the class of compounds identified as "a product of oxidation of urocanic acid with a reactive oxygen species or a salt thereof."

The amount of experimentation is not undue, as the specification shows a range of oxidation products having the activity. It shows that there are further oxidation products with activity (the difference between Im-mix and POmixIII) and it shows means for separating and isolation the products as the experimental part shows the successful completion of three of such attempts (pages 19 and 20).

Considering now the anticipation rejections, the Examiner has rejected claim 18 under 35 U.S.C. §102 (b) as allegedly anticipated by Roberts. The Examiner asserts that Roberts teaches use of imidazole-4-acetic acid as an analgesic. The Examiner admits that the reference says nothing about modulating immune response, but asserts that this property must be "inherently presented in the reference method." The Examiner argues that since "the administration of the same compound to the same ... recipient... would inherently possess the claimed therapeutic utility," it seems reasonable to conclude that the reference anticipates the claimed invention, even

absent explicit recitations of the mechanism of action.

Applicants respectfully traverse this rejection, and maintain that Roberts does not anticipate the claimed invention. Roberts injected indolacetic acid into mice to induce sleep and analgesia. No mention is made of any immune modulating abilities of the composition. Moreover, there is no commercial product mentioned by the Examiner, so it cannot be said that the composition was ever administered to a subject population in a dosage or from that modulated an immune response. There is simply insufficient evidence in Roberts for the Examiner to reply upon that reference as support an anticipation rejection based upon alleged inherency under 35 U.S.C. §102 (b).

Likewise, the anticipation rejection based upon Hart must fail as well. The amended claims are directed to the product oxidation of urocanic acid with a reactive oxygen species, or a salt thereof. Oxalic acid does not anticipate the amended claims. Withdrawal of the anticipated rejection based on Hart is respectfully requested.

Applicant: Arthur KAMMEIJER et al.  
U.S. Serial No.: 10/019,510  
Filed: December 21, 2001  
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The Commissioner is hereby authorized to charge any fees which may be required in consideration of the filing of this Response and to credit any overpayment to our Deposit Account No. 03-3125.

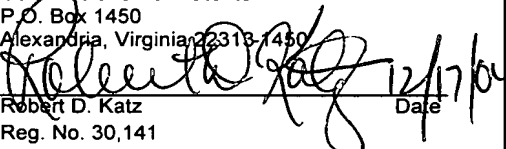
Respectfully submitted,

By 

Dated: December 17, 2004

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